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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,093	09/04/2003	Yutaka Umehara	302962 81476	6886

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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/655,093

Applicant(s)

UMEHARA ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-18,20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-18,20 and 22-24 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/28/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1, 3-8, 10-18, 20, and 22-24 are presented for reconsideration on the merits.

Miscellaneous Papers

The change of address filed February 2, 2005, and power of attorney filed February 17, 2005, have been received and entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 28, 2005, was filed after the mailing date of the first office action on December 14, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The amendment and extension of time filed therewith on April 7, 2005, have been received and entered. The remarks filed April 7, 2005 have also been entered of record and will be considered herein. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 6 is objected to for the misspelling of particles, note line 3.

Claim Rejections - 35 USC § 112

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Claims 14-18, 20, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-18, 20 and 22 are rendered vague and indefinite for failing to recite what the method is for, per se. Therefore, the metes and bounds of the claims can not be determined. It is suggested that Applicants insert after "method" in claim 14, line 1, the terminology as follows: --of producing a cell matrix-- and further to delete "," at line 1 of claim 14 as well.

Claims 16 and 22 are rejected for reasons of record for the recitation of "at least partially".

Response to Arguments

Applicant's arguments filed April 7, 2005, have been fully considered but they are not persuasive. The argument that the amendment made to claim 14 overcomes the rejection in noted, however, the amendment has created a new issue under 35 USC 112, second paragraph, as set forth above. Also Applicants did not set forth any rebuttal remarks with respect to the rejection of claim 16 and have presented a new claim 22, which is also rejected for the same reasons of record for claim 16. Therefore, these claims 14-18, 20 and 22 are rendered vague and indefinite for reasons noted above.

Claim Rejections - 35 USC § 102

Claims 1 and 3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Badylak et al (US Patent No. 5,516,533), cited of record, note pages 3-4 of the prior Office action of December 14, 2004.

Claims are drawn to a cell culture matrix composition comprising a tissue powder derived from an intestinal segment and the composition may further comprise a medium.

Badylak et al, cited above, teach a cell culture matrix composition comprising a tissue powder derived from an intestinal segment and the composition may further comprise a medium. Note column 2, lines 45-61. The disclosed medium is water or buffered saline which may be optionally added to the composition.

The claims are identical to the disclosure of Badylak et al and are therefore, considered to be anticipated by the teachings thereof.

Response to Arguments

Applicant's arguments filed April 7, 2005, have been fully considered but they are not persuasive. The argument that the whole segment is required by the claims is noted, however, Applicants claims actually require a portion of a whole tissue, which reads on an intestinal segment tissue as disclosed by Badylak et al. Applicants' own specification at page 5, lines 14-17, define the term "whole" to denote that the biological materials are not decellularized or digested prior to being processed into a cell support matrix. While Applicants have amended the instant claims to include full and intact

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organs or a portion thereof, the whole teaching of the specification clearly describes that a full and intact organ is not necessarily processed.

The cited disclosure clearly teaches that the intestine segment used to prepare the disclosed cell matrix composition does not have to be digested and is comminuted by tearing, cutting, grinding, shearing and the like, note column 2, lines 52-53.

Furthermore, the open ended term "comprising" does not necessarily omit a tissue powder derived from intestinal segment as disclosed by Badylak et al. The "whole segment" for which Applicants argue as the claimed critical feature for their invention is clearly anticipated by Badylak et al teachings of their cell culture matrix derived from the intestinal submucosa comprising a segment of intestinal tissue, see the abstract, line 9. For these reasons and those of record Applicants' arguments are not deemed persuasive.

Claims 4-5, 11 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Badylak et al, as cited above and of record in prior action, note above, at pages 4-5.

Applicant's arguments filed April 7, 2005, have been fully considered but they are not persuasive. The cited disclosure clearly teaches that the intestine segment used to prepare the disclosed cell matrix composition does not have to be digested and is comminuted by tearing, cutting, grinding, shearing and the like, note column 2, lines 52-53. Furthermore, the open ended term "comprising" does not necessarily omit a tissue powder derived from intestinal segment as disclosed by Badylak et al.

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The "whole segment" for which Applicants argue as the claimed critical feature for their invention is clearly anticipated by Badylak et al teachings of their cell culture matrix derived from the intestinal submucosa comprising a segment of intestinal tissue, see the abstract, line 9. Within the meaning of "whole segment" as argued by Applicants to be their criticality of the claimed invention, the term "whole" is not intended to imply that a full and intact organ is necessarily processed but that the "whole" organ, tissue or portion thereof is processed in undigested form, whether the organ is a full and intact organ or tissue, or only a portion thereof, see Applicants specification at page 5, lines 17-23. For these reasons and those of record Applicants' arguments are not deemed persuasive.

Claims 1, 3, 4-5, 11, 13-15, 20 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Badylak et al (US Patent No. 5,866,414), see enclosed PTO-1449 Form.

Claims are drawn to cell culture matrix composition comprising a tissue powder, method of producing the tissue powder, and method of producing a cell culture matrix and wherein the matrix composition contains portion of a whole liver and medium.

Badylack et al teach cell culture matrix composition comprising a tissue powder, method of producing the tissue powder, and method of producing a cell culture matrix and wherein the matrix composition contains portion of a whole liver and medium. See the abstract, and column 2, lines 10-16, line 65; column 3, line 61 and 62; column 6, lines 4-22 and 40-48.

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The claims are identical to the cited disclosure of Badylak et al and are considered therefore, to be anticipated by the teachings therein.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-6, 8, 11, 13 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by newly cited Yang, see enclosed PTO-1449 Form.

Claims are drawn to cell culture matrix composition comprising tissue powder and method for producing the tissue powder.

Yang teaches cell culture matrix composition comprising tissue powder and method for producing the tissue powder, see abstract and page 2, column 2, [0033], line 3, page 3, [0045], lines 1-30, page 6, [0084], line 5, page 7, [0087], all lines.

The claims are identical to the cited disclosure of Yang and are considered to be anticipated by these teachings therein. Yang clearly teach a segment of blood vessel from which a powder is derived as the tissue composition.

Claim Rejections - 35 USC § 103

Claims 1, 3-8, 10-18, 20, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al, Weiss et al and Vail et al, all cited of record, for reasons set forth in prior action of December 14, 2004, see pages 6-7.

Response to Arguments

Applicant's arguments filed April 7, 2005, have been fully considered but they are not persuasive. The argument that Badylak et al do not teach or suggest the newly amended claims is noted. However, as discussed above, the intestinal tissue disclosed by Badylak et al is not less than a portion, and even if one of skill can optionally read and interpret the cited disclosure as Applicants have, then within the meaning of Applicants' own definition of "whole" as discussed above one of skill would have been motivated to use a portion of intestinal tissue as disclosed by Badylak et al because the reference teaches that the powder is obtained without digestion of the tissue.

Furthermore, sonication and perfusion are clearly disclosed by the cited prior art secondary references and one of skill would have been motivated to use these techniques because they are disclosed to be useful for the preparation of similar products as claimed herein. The prior art at least suggests the process steps as claimed herein, if not teaches them, and one of skill in the art would have a reasonable expectation of successful results employing these method steps for providing a cell culture matrix composition comprising a tissue powder from a biological material. The claims remain *prima facie* obvious.

Applicant's amendment and IDS with fee necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

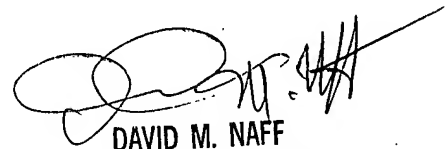
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah K. Ware
July 23, 2005



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651